



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

OCT 15 2004

Anabolic Laboratories, Inc.  
Attention: Robert van Osdel  
17802 Gillette Avenue  
Irvine, CA 92614-6502

Docket No. 2003P-0461/CP1

Dear Mr. van Osdel:

This is in response to your petition filed on October 1, 2003, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Cyclobenzaprine Hydrochloride Tablets, 7.5 mg. The reference listed drug product to which you refer in your petition is Flexeril® (Cyclobenzaprine HCl) Tablets, 5 mg and 10 mg, approved under NDA 17-821 held by McNeil Consumer & Specialty Pharmaceuticals. Please be advised that, pursuant to 21 CFR 314.93, the petitioner shall identify a listed drug as the drug of reference for requested changes. For your information, the reference listed drug as identified in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" is Flexeril® (Cyclobenzaprine HCl) Tablets, 10 mg.

Your request involves a change in strength from that of the reference listed drug product, i.e., from 5 mg and 10 mg to 7.5 mg. The change you request is the type of change that is authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug product. In addition, we have reviewed the comments dated November 5, 2003 submitted by McNeil Consumer & Specialty Pharmaceuticals.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a strength that differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The Agency finds that the change in strength for the specific proposed drug product does not pose questions of safety or effectiveness because the uses, dose, and route of administration of the proposed drug product are the same as that of the listed drug product. The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

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Anabolic Laboratories, Inc.

Cyclobenzaprine Hydrochloride Tablets, 7.5 mg

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the Agency has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol for this drug product to the Office of Generic Drugs, Division of Bioequivalence, prior to the submission of your ANDA. During the review of your application, the Agency may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary Buehler", with a long horizontal flourish extending to the right.

Gary J. Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research